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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/767,283	01/22/2001	Gary D. Glick	128019-203802	2710

7590

06/16/2006

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EXAMINER

KIM, VICKIE Y

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 06/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/767,283

Applicant(s)

GLICK ET AL.

Examiner

Vickie Kim

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– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 130-133 and 138-140 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 130-133 and 138-140 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/06 and 1/06</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Status of Application

1. Acknowledgement is made of amendment filed 5/15/06. Upon entering the amendment, the claims 130-133, 138-140 are amended and the claims 1-129, 134-137 are canceled.
2. The claims 130-133, 138-140 are pending and presented for the examination.

Information Disclosure Statement(IDS)

The information disclosure statement (IDS) is submitted on 4/27/06 and 1/25/06. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. Please refer to applicants' copy of the 1449 submitted herewith.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

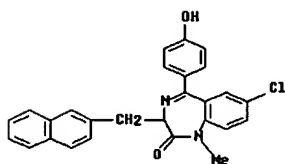
2. Claims 130-133 and 138-140 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al(1998, Synthesis of 3-substituted...) in view of Applicant's own disclosure and Nakao(US5141930).

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The claims are drawn to a compound having the structure as claimed in claim 130.

Kim et al(1998) teach a 3-substituted 1,4-Benzodiazepin-2-ones such as a compound 1 (see at page 375, Bz-423). Kim's compound(i.e. Bz-423) meets all the claims except 1-aliphatic group substitution where the aliphatic group has at least 2 carbons. The claims are amended to exclude 1-methyl N substitution (Bz-423) .

Bz-423 is as following:



Although applicant excludes Bz-423(1-methyl substitution), as evidenced by applicant's own disclosure as well as numerous documents available in patent and non-patent literature, the elongation of alkyl group from methyl to other lower alkyl groups(e.g. ethyl or propyl) is commonly practiced to extend the effective species, and thus said substitution is obvious. The teaching of Kim et al does render the claimed invention obvious and does not render the claims patentably distinct from the compound taught, absent evidence to the contrary, especially because the techniques and skills are well taught by cited references(see supporting documents enclosed in PTO-892) and one would have been motivated to extend the species to include not only methyl but also ethyl, propyl, butyl,(lower alkyl groups) because the efficacy is well proven and suggested by both instant disclosure and prior art of the record(see instant disclosure at page 32, second example containing 1-methyl substitution).

Kim et al teach that the preparation has been formulated for animal study. Thus, one would have been envisioned the pharmaceutical composition using the said compound 1 suitable for carrying out the administration to animal.

The deficiency of Kim's teaching can also be remedied by Nakao et al(US5141930) because Nakao teaches benzodiazepine compounds with N-substitution by methyl or any other aliphatic group(including ethyl substitution), wherein the efficacy of the compound is substantially same and Nakao teaches the techniques and skills required for said substitution, see abstract and table 1 at cols 41-42.

One would have been motivated to do so, with reasonable expectation of success because it is always desirable to have extended therapeutic modalities to increase industrial applicability and selection option to benefit manufacturing process. As mentioned earlier, the techniques and skills required for making such substitution is conventional knowledge or well within the skills of ordinary artisan as evidenced by both instant disclosure as well as cited references.

Conclusion

3. No claim is allowed. Having carefully reviewed applicants' Request for Reconsideration, the examiner maintained the rejection in any respect.

1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

4. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 571-272-0579. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

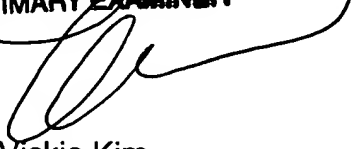
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you have questions on access to the Private PAIR system, contact the Electronic
Business Center (EBC) at 866-217-9197 (toll-free).

VICKIE KIM
PRIMARY EXAMINER



Vickie Kim
Primary Patent Examiner
June 11, 2006
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